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OBJECTIVES: Chronic pain is a common and universal phenomenon that appears at all ages and in all populations. It has a substantial impact on the quality of patients' daily life as well as their physical and mental function. The objective of this study was to document attributes of a pain medication that are relevant from the perspective of patients with chronic pain. **METHODS:** In a first step literature review, focus groups with patients and one to one interviews with highly accepted experts in the field of indication were conducted to identify relevant treatment attributes of a pain medication. A pretest was conducted to verify the structure of relevant and dominant attributes using factor analysis and choosing the most frequent mentioned representative of each factor. The discrete choice experiment (DCE) itself used a self administered survey including sociodemographics and an indication specific parameter (pain). For statistical data analysis of the DCE, a random effect logit model was used and coefficients were presented. **RESULTS:** In a first step we detected 36 attributes. Factor analysis revealed seven remaining attributes. A total of N=1324 German patients participated in the self administered survey, resulting in the following ranking of relevant attributes for treatment decision: "no character change", "less nausea and vomiting", "pain reduction" (Coefficient: > 0.9 for all attributes, "high impact"); "rapid effect", "less danger of addiction" (Coefficient ~ 0.5, "middle impact"); "applicability with comorbidity" (Coefficient: ~ 0.3), "improvement of quality of sleep" (Coefficient ~ 0.25). All attributes were highly significant ($p < 0.001$). **CONCLUSIONS:** Due to the subjective nature of pain, the management of chronic pain needs to be patient centered. Therefore an understanding of patient preferences is essential for inclusion in treatment decisions. In summary, DCE and direct assessment proved to be valid instruments to elicit treatment preferences in chronic pain treatment.

PSY43

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE – WEIGHT (TRIM-WEIGHT)

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OBJECTIVES: The TRIM-Weight is a Patient-Reported Outcome (PRO) questionnaire designed to assess the efficacy and tolerability of weight loss medication. The objective of this study was to produce translations into number of languages that are conceptually equivalent to the original and to other language versions, ensuring the validity of the translations within the target cultures. **METHODS:** The standard linguistic validation methodology was followed: two forward translations with reconciliation, two back translations and review, developer review, cognitive interviews with five obese people for each language, and proof reading. **RESULTS:** Numerous cultural and linguistic issues became apparent throughout the translation process, including the following: The term for 'craving' proved difficult to translate into Spanish, Italian, French (France) and French (Canada). The developer's input and cognitive debriefing interviews were used to find appropriate terminology to convey the intended meaning. For example, it had to be specified in French (France) that this related to one particular food; 'jitteriness' was mentioned in the scale as a physical side-effect of the drug; this word was problematic in Dutch (where the translator had to use a term related to 'trembling'), and Brazilian Portuguese (where the translator used a term related to being physically anxious and unable to relax); Brazilian respondents had difficulty understanding that they must respond only concerning prescription weight loss medication and the related instruction had to be underlined to clarify this; several vocabulary problems occurred, e.g. finding terms for 'isolated' in Russian, 'embarrassment' in Brazilian Portuguese and 'weight loss plateaus' in Austria German. Each issue was discussed until a suitable alternative was found which could be tested in cognitive interviews with patients. **CONCLUSIONS:** The TRIM-Weight questionnaire was translated and linguistically validated using a rigorous translation process. A number of cultural and linguistic issues became apparent and were resolved. TRIM-Weight is now validated for use in multinational trials.

PSY44

ASSOCIATION OF THE OBESITY AND WEIGHT-LOSS QUALITY-OF-LIFE SCORE WITH PATIENT DEMOGRAPHICS AND MEASURES OF OBESITY

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OBJECTIVES: As the incidence of obesity continues to rise, there is pressure to find and evaluate new weight loss interventions; understanding the impact of obesity and weight loss on patients is an invaluable part of this process. We aimed to examine associations among patient characteristics, self-reported depression, vitality and the obesity and weight-loss quality-of-life (OWL-QOL) instruments in a population of overweight and obese patients. **METHODS:** We analysed baseline data from a clinical trial involving patients with body mass index (BMI) between 27–45 kg/m². Data included: patient demographics; obesity measures including BMI, weight and body composition; responses to the OWL-QOL questionnaire; responses to the Patient Health Questionnaire (PHQ), assessing depression; and responses to the SF-36 vitality subscale. Least angle regression (LAR) was used to select the most relevant obesity measures to include in multivariable regression models. Univariate associations were examined using Spearman's correlations. **RESULTS:** Baseline data were available for 341 patients with a mean age of 44.2 (SD=10.7) years, mean BMI of 35.2 (SD=4.67) kg/m², and mean OWL-QOL total score of 55.3 (SD=24.2). 83.3% were female. LAR showed that among obesity measures, percentage of total fat was most significantly associated with the OWL-QOL total score. Based on Spearman's correlations, the OWL-QOL total score was significantly

cantly correlated with gender ($\rho=0.233$, $p<0.001$), total fat ($\rho=-0.264$, $p<0.001$), PHQ ($\rho=-0.138$, $p=0.035$), and vitality ($\rho=0.456$, $p<0.001$). In the final model ($R^2=0.34$), vitality ($\beta=0.55$, $p<0.001$), female gender ($\beta=-8.71$, $p=0.026$) and race/ethnicity ($\beta=12.3$, African American versus Other, $\beta=1.08$ White versus Other; $p=0.002$ for both comparisons), but not percentage of total fat, were significantly associated with the OWL-QOL total score. **CONCLUSIONS:** The OWL-QOL was significantly associated with gender, race/ethnicity and vitality. Importantly, based on LAR, percentage of total fat was more significantly associated with the OWL-QOL total score than other obesity measures, including BMI.

PSY45

IMPACT OF LUPUS ON CAREER CHOICES AND WORK PRODUCTIVITY IN FIVE EUROPEAN COUNTRIES: RESULTS FROM THE LUPUS EUROPEAN ONLINE (LEO) SURVEY

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OBJECTIVES: A previous survey distributed in Europe and the US found that lupus affects patients' career, physical well-being and everyday living. The LEO survey was developed to explore further the effect of lupus on work productivity, fatigue and health-related quality of life (HRQoL) in Europe. **METHODS:** The survey had four sections. Section 1 included patient-developed questions on demographics, lupus diagnosis and impact of lupus on work and career. Sections 2–4 used lupus-specific patient-reported outcomes (PRO) instruments to assess work impairment (Work Productivity and Activity Impairment Questionnaire, Lupus V2.0), fatigue (lupus-specific Fatigue Severity Scale) and HRQoL (LupusQoL). The survey was available May–August 2010 and in five European languages. **RESULTS:** A total of 1566 participants with self-reported lupus completed the survey: from France ($n=139$), Germany ($n=537$), Italy ($n=357$), Spain ($n=267$) and the UK ($n=266$). Most were female (93%, 1440/1557) and aged 26–55 years (81%, 1253/1550). In section 1, over two-thirds (70%, 1028/1475) of participants reported that lupus affected their career (highest UK, 79% [199/252]; lowest France, 56% [73/131]). Of these, 31% (288/928) now work flexible hours, 29% (265/928) applied for sick leave, 24% (219/928) applied for social or disability allowance and 17% (156/928) changed career. Of those who reduced work hours, almost a quarter (23%, 150/646) had to reduce by >75%. In the WPAI assessment, participants reported missing an average of 13% (SD=24.2) of their working time because of lupus. At work, productivity was reduced by an average of 40% (SD=25.8). Overall, an average of 43% (SD=27.1) of total work hours available to participants were lost due to lupus. Ability to carry out non-work activities such as housekeeping, childcare and studying was, on average, impaired by 56% (SD=26.7). **CONCLUSIONS:** Lupus diminishes European patients' likelihood of working and their productivity while at work. These findings emphasise the need for improved management of lupus.

PSY46

COMPARISON OF EQ-5D AND SF-6D UTILITIES IN POMPE DISEASE

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OBJECTIVES: Comparative studies between EuroQoL-5D (EQ-5D) and Short-form 6D (SF-6D) utilities have been performed for a number of diseases, but not for patients with Pompe disease. Pompe disease is a rare disease (prevalence of <5/10,000). Characteristic features of late onset Pompe disease are impaired ambulatory and respiratory functioning. We compared the psychometric properties of EQ-5D and SF-6D in these patients and assessed the convergent validity and the ability of the instruments to discriminate with respect to functional capabilities and subjective health. **METHODS:** EQ-5D utilities were calculated using the Dutch value set. EQ-5D and SF-6D domains and utilities were compared by correlation coefficients and descriptive statistics. We assessed whether EQ-5D and SF-6D were able to discriminate between different levels of Pompe disease severity as defined by subjective health status (SF36 rating scale and Visual Analogue Scale (VAS) divided into tertiles) and functional capabilities (use of wheelchair and respiratory support). **RESULTS:** Eighty-two patients (82% of the total Dutch Pompe population) completed both EQ-5D and SF-6D (average follow-up 3.8 observations; 3.1 years). Correlations between theoretically related domains were highly significant and moderately strong (range $\rho=0.392$ – $\rho=0.632$). The SF-6D domain "vitality" had no EQ-5D counterpart. Utility values were comparable (mean EQ-5D = 0.739; mean SF-6D = 0.710), and moderately correlated ($r=0.544$). Discriminative properties of EQ-5D and SF-6D were comparable; patients using wheelchair, or respiratory support and patients with a lower VAS score reported lower EQ-5D and SF-6D utilities. **CONCLUSIONS:** The descriptive system of the SF-6D described Pompe disease more accurate. Discriminative properties of EQ-5D and SF-6D outcomes were similar in this population.

PSY47

EVALUATING THE CROSS-OVER EFFECT ON HEALTH-RELATED QUALITY OF LIFE IN A RANDOMIZED CROSS-OVER STUDY OF HEMOPHILIA-A PATIENTS

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OBJECTIVES: To investigate the cross-over effects on health-related quality of life (HRQoL) in an randomized cross-over design study for hemophilia-A patients. **METHODS:** HRQoL via SF-36 Health Survey was measured every 3 months in a prospective, randomized, cross-over, investigator-initiated study comparing 6